

## LARYNGEAL MASK

### CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of U.S. Patent Application Serial No. 09/829,157,  
5 filed April 9, 2001, which is a continuation-in-part of U.S. Patent Application Serial No.  
09/179,928, filed on October 27, 1998, and issued as U.S. Patent No. 6,422,239 on July  
23, 2002, which is a divisional of U.S. Patent No. 5,937,860, which issued on August 17,  
1999.

### 10 STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

### BACKGROUND OF THE INVENTION

This invention relates to an artificial airway device designed to facilitate lung  
ventilation and the insertion of endotracheal tubes or related medical instruments into the  
15 laryngeal opening of an unconscious patient, and more specifically to a laryngeal mask  
designed to be placed within the oropharynx region over the laryngeal opening to conceal  
the circumference of the laryngeal opening against the aspiration of regurgitated gastric  
content and provide a direct pathway from a perimeter exterior to the oral cavity to the  
laryngeal opening.

20 In general, laryngeal masks allowing for both rapid lung ventilation and the  
insertion of medical instruments and tubes into the laryngeal openings of patients have  
been described in patents such as U.S. Patent No. 4,509,514 to Brain. Consisting of two  
essential parts, a breathing tube and an inflatable mask, these devices are inserted blindly

into a patient's throat, and when properly positioned, terminate at the laryngeal opening.

Generally, a seal is then formed around the circumference of the laryngeal opening by the inflation of a ring-like structure located on the front of the mask. Inflation of the ring exerts pressure against both the front and rear portions of the oropharynx, securing the device in place such that the laryngeal opening is positioned within the cavity in the mask face. Extending from a point external to the oral cavity, the flexible breathing tube terminates within the cavity, which is aligned axially with the laryngeal opening. The positioning of the flexible breathing tube allows the passage of small diameter endotracheal tubes or related medical instruments into the laryngeal opening, in addition to allowing for lung ventilation.

Current laryngeal masks have several drawbacks in the area of placement, lung ventilation, and endotracheal intubation. For example, during insertion and positioning, the flexible nature of the deflated ring structure and surrounding mask allows the distal end of the mask to bend back on itself, making placement difficult. Also, once installed, the current mask designs fail to exert sufficient pressure against the larynx necessary to maintain proper positioning during intubation and ventilation. This is due to the variations in the anatomy of the oropharynx region and the curvature of the device itself. Further, during lung ventilation it is possible for the tip of the epiglottis to become lodged in the distal lumen of the flexible breathing tube, which inhibits the passage of air or endo-tracheal tubes through the tube. This problem is often overcome by the placement of a series of band structures at the entrance of the distal lumen that prevent the epiglottis from entering the breathing tube. However, these band structures severely restrict the size of the endo-tracheal tubes or related medical devices that may be passed through the

flexible breathing tube. Moreover, after insertion of an endo-tracheal tube or related medical device, it becomes difficult to remove the laryngeal mask from the patient's oropharynx without dislodging or accidentally extracting the endo-tracheal tube or medical device along with the laryngeal mask.

- 5           Accordingly a laryngeal mask that provides generally the same function as described above is needed that allows a more secure insertion and airtight placement, allows the unrestricted passage of large diameter endo-tracheal tubes directly into the laryngeal opening, and provides alternative airways.

#### SUMMARY OF THE INVENTION

- 10           Briefly stated, a laryngeal mask of the type used to facilitate lung ventilation and the insertion of endotracheal tubes or related medical instruments through a patient's laryngeal opening as used during general anesthesia, intensive care, or critical patient care is provided that includes an inflatable positioning shield formed to fit within the patient's oropharynx, the positioning shield having an inflatable, hollow peripheral
- 15   portion, and a posterior base in fluid communication with the peripheral portion, a shield recess formed after inflation of the peripheral portion, and a rear portion formed between the posterior base and the peripheral portion after inflation of the peripheral portion, wherein the posterior base has a recessed front portion, and a respiratory tube having a proximal end lumen, a curved tubular body of sufficient size to permit passage of endo-
- 20   tracheal tubes or related medical instruments therethrough, and a distal end passing through and secured to the rear portion of the positioning shield, the distal end terminating at a distal lumen, the distal lumen passing through and secured to the rear

portion of the positioning shield such that tubes and instruments passing through the respiratory tube will be directed into the laryngeal opening;

In a second aspect of the invention, the above-described laryngeal mask comprised of a respiratory tube that has an elliptical cross-section, where the cross-  
5 section is perpendicular to the longitudinal axis of the tube;

In a third aspect of the invention, the above-described laryngeal mask comprises a distal lumen that has an elliptical cross-section, where the cross-section is perpendicular to the longitudinal axis of the tube;

In a fourth aspect of the invention, the laryngeal mask comprises a distal lumen  
10 that has an upper portion and a lower portion, wherein the upper portion and the lower portion have about the same diameter, the diameter of the upper portion and the lower portion being smaller than the diameter of the proximal end lumen;

In a fifth aspect of the invention, the above described laryngeal mask comprises a distal lumen that has an upper portion and a lower portion, wherein the upper portion and  
15 the lower portion have about the same diameter, the diameter of the upper portion and the lower portion being smaller than the diameter of the proximal end lumen, wherein the distal lumen is sufficiently pliable such that it opens upon the assertion of pressure thereon and returns to its original shape when the pressure is released;

In a sixth aspect of the invention, the above described laryngeal mask comprises a  
20 distal lumen that has an upper portion and a lower portion, wherein the upper portion has a diameter that is different from the diameter of the lower portion;

In a seventh aspect of the invention, the above-described laryngeal mask further comprises at least one raised horizontal runner that is a continuous extension of the posterior base;

In an eighth aspect of the invention, a laryngeal mask of the type used to facilitate lung ventilation and insertion of endo-tracheal tubes or related medical instruments through a patient's laryngeal opening as used during general anesthesia, intensive care, or critical patient care is provided that includes an inflatable positioning shield formed to fit within the anatomical structures of the oropharynx region when inflated, the positioning shield enclosing the laryngeal opening within a recessed front, and having an inflatable, hollow peripheral portion, the recessed front being sufficiently pliable to cup the patient's tracheal after inflation of the positioning shield, and a respiratory tube having a proximal end lumen, a curved tubular body having an elliptical cross-section, and being sufficiently radially deformable to permit passage of endo-tracheal tubes or related medical instruments therethrough, and a distal end passing through and secured in an airtight manner to the rear portion of the positioning shield, terminating at a distal lumen within the rear portion of the positioning shield so as to be aligned axially with the laryngeal opening upon insertion into the oropharynx, wherein the cross-section is perpendicular to the longitudinal axis of the tube;

In a ninth aspect of the invention, a laryngeal mask of the type used to facilitate lung ventilation and the insertion of endo-tracheal tubes or related medical instruments through a patient's laryngeal opening as used during general anesthesia, intensive care, or critical patient care is provided that comprises an inflatable positioning shield curved to fit within the patient's oropharynx, the positioning shield having an inflatable, hollow

peripheral portion, a posterior base in fluid communication with the peripheral portion, a shield recess formed after inflation of the peripheral portion, and a rear portion formed between the posterior base and the peripheral portion after inflation of the peripheral portion, wherein the posterior base has a recessed front portion, the recessed front portion being sufficiently pliable to cup the patient's trachea after inflation of the positioning shield, thereby limiting lateral movement of the laryngeal mask, and a respiratory tube having a proximal end lumen, a curved tubular body of sufficient size to permit the passage of endo-tracheal tubes and related medical instruments therethrough, and a distal end passing through and secured to the rear portion of the positioning shield, the distal end terminating at a distal lumen, wherein the distal lumen passes through and is secured to the rear portion of the positioning shield such that tubes or related medical instruments passing through the respiratory tube will be directed into the laryngeal opening, wherein the recessed front portion of the posterior base comprises at least one raised horizontal runner that is a continuous extension of the posterior base, and wherein the distal lumen comprises an upper portion and a lower portion, wherein the upper portion and the lower portion have about the same diameter, the diameter of the upper portion and the lower portion being smaller than the diameter of the proximal end lumen;

In a tenth aspect of the invention, a laryngeal mask of the type used to facilitate lung ventilation and the insertion of endo-tracheal tubes or related medical instruments through a patient's laryngeal opening as used during general anesthesia, intensive care, or critical patient care is provided that comprises an inflatable positioning shield formed to fit within a patient's oropharynx, the positioning shield having an inflatable, hollow peripheral portion, a posterior base in fluid communication with the peripheral portion, a

shield recess formed after inflation of the peripheral portion, and a rear portion formed between the posterior base and the peripheral portion after inflation of the peripheral portion, wherein the posterior base has a recessed front portion that is sufficiently pliable to cup the patient's trachea after inflation of the positioning shield and a respiratory tube having a proximal end lumen, a curved tubular body of sufficient size to permit passage of endo-tracheal tubes and related medical instruments therethrough, and a distal end passing through and secured to the rear portion of the positioning shield, the distal end terminating at a distal lumen, the distal lumen passing through and secured to the rear portion of the inflatable positioning shield such that tubes or other related medical instruments passing through the respiratory tube will be directed into the laryngeal opening, wherein the recessed front portion of the posterior base comprises at least one raised horizontal runner that is a continuous extension of the posterior base, wherein the distal lumen comprises an upper portion and a lower portion wherein the upper portion and the lower portion, have about the same diameter, the diameter of the upper portion and the lower portion being smaller than the diameter of the proximal end lumen, and wherein the distal lumen is sufficiently pliable such that it opens upon the assertion of pressure thereon and returns to its original shape when the pressure is released;

In an eleventh aspect of the invention, a laryngeal mask of the type used to facilitate lung ventilation and the insertion of endo-tracheal tubes or related medical instruments through a patient's laryngeal opening as used during general anesthesia, intensive care, or critical patient care is provided that comprises an inflatable positioning shield formed to fit within a patient's oropharynx, the positioning shield having an inflatable, hollow peripheral portion, a posterior base in fluid communication with the



peripheral portion, a shield recess formed after inflation of the peripheral portion and a rear portion formed between the posterior base and the peripheral portion after inflation of the peripheral portion, wherein the posterior base has a recessed front portion, the recessed front portion being sufficiently pliable to cup the patient's trachea after inflation

5 of the positioning shield, and a respiratory tube having a proximal end lumen, a curved tubular body of sufficient size to permit passage of endo-tracheal tubes and related medical instruments therethrough, and a distal end passing through and secured to the rear portion of the positioning shield, the distal end terminating at a distal lumen, the distal lumen passing through and secured to the rear portion of the positioning shield such

10 that tubes or related medical instruments passing through the respiratory tube will be directed into the laryngeal opening, wherein the distal lumen comprises an upper portion and a lower portion, the upper portion having a diameter that is different from the diameter of the lower portion;

In a twelfth aspect of the invention, a laryngeal mask of the type used to facilitate

15 lung ventilation and the insertion of endo-tracheal tubes or related medical instruments through a patient's laryngeal opening as used during general anesthesia, intensive care, or critical patient care is provided that comprises an inflatable positioning shield formed to fit within a patient's oropharynx, the positioning shield having an inflatable, hollow peripheral portion, a posterior base in fluid communication with the peripheral portion, a

20 shield recess formed after inflation of the peripheral portion and a rear portion formed between the posterior base and the peripheral portion after inflation of the peripheral portion, wherein the posterior base has a recessed front portion, the recessed front portion being sufficiently pliable to cup the patient's trachea after inflation of the positioning



shield, thereby limiting lateral movement of the laryngeal mask, and a respiratory tube having a proximal end lumen a curved tubular body of sufficient size to permit passage of endo-tracheal tubes and related medical instruments therethrough, and a distal end passing through and secured to the rear portion of the positioning shield, the distal end  
5 terminating at a distal lumen, the distal lumen passing through and secured to the rear portion of the positioning shield such that tubes and related medical instruments passing through the respiratory tube will be directed into the laryngeal opening, wherein the distal lumen comprises an upper portion and a lower portion, wherein the upper portion has a larger diameter than the diameter of the lower portion, and wherein the distal end of the  
10 respiratory tube comprises at least one lumen, the at least one lumen having a diameter that is smaller than the diameter of the proximal end lumen; and

In a thirteenth aspect of the invention, a laryngeal mask of the type used to facilitate lung ventilation and the insertion of endo-tracheal tubes or related medical instruments through a patient's laryngeal opening as used during general anesthesia,  
15 intensive care, or critical patient care is provided that comprises an inflatable positioning shield formed to fit within a patient's oropharynx, said positioning shield having an inflatable, hollow peripheral portion, a pliable base in fluid communication with the peripheral portion, a shield recess formed after inflation of the peripheral portion and a rear portion formed between the posterior base and the peripheral portion after inflation  
20 of the peripheral portion, wherein the posterior base has a recessed front portion that is sufficiently pliable to cup the patient's trachea after inflation of the positioning shield and a respiratory tube having a proximal end lumen, a curved tubular body of sufficient size to permit passage of endo-tracheal tubes and related medical instruments therethrough,

and a distal end passing through and secured to the rear portion of the positioning shield,  
the distal end terminating at a distal lumen, the distal lumen passing through and secured  
to the rear portion of the positioning shield such that tubes and related medical  
instruments passing through the respiratory tube will be directed into the laryngeal  
5 opening, wherein the distal lumen comprises an upper portion and a lower portion,  
wherein the upper portion has a larger diameter than the lower portion, wherein the distal  
end of the respiratory tube comprises at least one lumen, the at least one lumen having a  
diameter that is smaller than the diameter of the proximal end lumen, and wherein the  
recessed front portion of the posterior base comprises at least one horizontal runner that is  
10 a continuous extension of the posterior base.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a top view of an embodiment of the laryngeal mask of the invention  
illustrating the flexible breathing tube and the inflatable positioning shield;

Figure 2 is a bottom plan view of one embodiment of the laryngeal mask of the  
15 invention;

Figure 3 is a front plan view of one embodiment of the laryngeal mask of the  
invention;

Figure 4 is a bottom view of the inflatable positioning shield of the invention;

Figure 5 is a sectional view of the inflatable positioning shield after inflation,  
20 illustrating the recessed front portion of the positioning shield and the unobstructed distal  
lumen of the flexible breathing tube;

Figure 6 is a rear view of the inflatable positioning shield after inflation, with the  
flexible breathing tube removed;

Figure 7 is an illustration of a patient's oral cavity, illustrating the elliptical shape of the opening into the laryngeal region;

Figure 8 is a front plan view of one embodiment of the laryngeal mask of the invention, illustrating the recessed front portion the positioning shield, the rear portion of the positioning shield, and the key-hole shape unobstructed distal lumen of the flexible breathing tube;

Figure 9 is a top plan view of the inflatable positioning shield after inflation, illustrating the recessed front portion of the positioning shield, the key-hole shaped unobstructed distal lumen of the flexible breathing tube, the raised horizontal runners and the small diameter lumens;

Figure 10 is a plan view of the endotracheal tube retainer, illustrating the end cap;

Figure 11 is a plan view of the endotracheal tube retainer, illustrating the separation of the tube retainer body from the connection adapter;

Figure 12 is a front view of the distal end of the connection adaptors, illustrating the airflow grooves;

Figure 13 is a plan view of the laryngeal mask of the invention during use, illustrating interaction with an endo-tracheal tube retainer;

Figure 14 is a plan view of an endo-tracheal tube retainer during use, illustrating proper positioning of the tube retainer; and

Figure 15 is a plan view of the laryngeal mask during removal, illustrating the operation of the endotracheal tube retainer.

Corresponding reference numerals indicate corresponding parts throughout the several figures of the drawings.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following detailed description illustrates the invention by way of example and not by way of limitation. The description will clearly enable one skilled in art to make and use the invention, describe several embodiments, adaptations, variations, alternatives, and uses of the invention including what is believed to be the best mode of carrying out the invention.

Referring to the drawings, and particularly Figs. 1-3, a new and useful laryngeal mask 10 has been invented that provides generally the same function as current laryngeal masks, while avoiding some of the problems associated with their use. Specifically, the laryngeal masks 10 of the invention can be more securely and certainly inserted and removed, permitting the unrestricted passage of large diameter endotracheal tubes directly to the laryngeal opening, and providing alternate airways to prevent blockage of the breathing tube during patient ventilation. In accordance with the invention, a laryngeal mask 10 is provided that comprises an inflatable positioning shield 22 secured to distal end 24 of respiratory tube 26, forming a smooth arcuate curve. Inflatable positioning shield 22 is formed to fit within a patient's oropharynx. The positioning shield 22 of the invention has an inflatable, hollow peripheral portion 40, a pliable base 42 in fluid communication with the peripheral portion 40, a shield recess 36 formed after inflation of peripheral portion 40, and a rear portion 45 formed between posterior base 42 and the peripheral portion 40 after inflation of the peripheral portion 40. Posterior base 42 has a recessed front portion 43 to facilitate insertion and removal of inflatable positioning shield 22 into the patient's airway. Generally, and in one embodiment of the invention, posterior base 42 is comprised a material that imparts pliability thereto.

Respiratory tube 26 comprises a proximal end lumen 30, a curved tubular body of sufficient size to permit passage of endotracheal tubes or related medical instruments therethrough, and a distal end 24 passing through and secured to the rear portion 45 of the positioning shield. Distal end 24 of respiratory tube 26 terminates at a distal lumen 32, which passes through and is secured to the rear portion 45 of the positioning shield such that tubes and instruments passing through respiratory tube 26 will be directed into the laryngeal opening. Respiratory tube 26 may have any cross-section shape, provided that medical instruments are not prevented from passing therethrough. In one embodiment, respiratory tube 26 has an oval cross-sectional shape, where the cross-section is perpendicular to the longitudinal axis of the tube 26. In another embodiment, respiratory tube 26 has a circular cross-sectional shape, where the cross-section is perpendicular to the longitudinal axis of the tube 26.

Inflatable positioning shield 22 comprises an inflatable, hollow peripheral portion 40. Inflation of positioning shield 22 is accomplished by means of any conventional inflation device. These devices are readily available and known in the art. Generally, and with reference to Figure 1, peripheral portion 40 comprises a means for allowing inflation 48 thereof that is generally located in a proximal area of peripheral portion 40, near distal end 24 of respiratory tube 26. However, the means for allowing inflation 48 may be in any convenient location, provided that inflation of peripheral portion 40 after insertion into a patient's airway is not hindered. The means for allowing inflation is generally a small aperture, which may be circular, oval or slot-shaped.

Peripheral portion 40 may be of any shape, so long as the shape does not prevent insertion of the positioning shield 22 into the patient's oropharynx. In a preferred

embodiment of the invention, peripheral portion 40 forms an ovoid, or wedge shape when inflated to conform to the approximate available space in the oropharynx region.

Posterior base 42 is secured in an airtight manner in fluid communication with peripheral portion 40 of inflatable positioning shield 22. Posterior base 42 forms an elongated and tapered hemisphere. Upon inflation of positioning shield 22, shield recess 36 is formed. Posterior base 42 comprises recessed front portion 43, which is sufficiently pliable to cup the patient's trachea after inflation of positioning shield 22, thereby limiting lateral movement of laryngeal mask 10.

Hollow inflatable positioning shield 22 is secured to distal end 24 of respiratory tube 26. Generally, and in one embodiment of the invention, respiratory tube 26 is comprised of a material that imparts flexibility thereto. Respiratory tube 26 may be manufactured using any material this is sufficiently flexible to allow insertion of the tube into the patient's airway. In one embodiment, respiratory tube 26 comprises a flexible silicone-rubber polymer. In another embodiment, respiratory tube 26 comprises polyvinylchloride. Generally, respiratory tube 26 is capable of spreading radially, and can accommodate the passage of endotracheal tubes and related medical devices up to 8.0 French in the diameter. However, it is contemplated that respiratory tube 26 can accommodate medical devices having larger diameters. However, it should be noted that respiratory tube 26 need not be flexible in accordance with the invention.

The length of respiratory tube 26 is such that when laryngeal mask 10 is properly positioned for use in the oropharynx, proximal or attachment end 28 of respiratory tube 26 is located exterior to the oral cavity. As is readily known in the art, respiratory tube 26 may comprise one or more lumens therein. Attachment end 28 of respiratory tube 26

terminates in unobstructed proximal lumen 30, providing a direct pathway to respiratory tube 26 to distal end 24 and distal lumen 32. In an alternative embodiment, attachment end 28 may be fitted with adaptors or connectors that are suitable for connection to the variety of medical devices, for example lung ventilation machine.

5           Respiratory tube 26 may be of any shape, provided that the shape does not inhibit the passage of endotracheal tubes and related medical devices into the laryngeal opening. In one embodiment of the invention, attachment end 28 of respiratory tube 26 has an elliptical cross-section, approximating the shape of the human throat as shown in Fig. 7. The cross-sections referred to herein and through this specification are perpendicular to  
10   the longitudinal axis of the component referred to.

          Distal end 24 is a continuous portion of respiratory tube 26, which has passed through rear portion 45 of inflatable positioning shield 22. Rear portion 45 is formed between posterior base 42 and peripheral portion 40 after inflation of peripheral portion 40. Distal end 24 terminates at an angle to its length forming the elongated distal lumen  
15   32, which is open to the interior of shield recess 36.

          Respiratory tube 26 is comprised of a curved tubular body of sufficient size to permit the passage of endotracheal tubes and related medical instruments therethrough. In one embodiment of the invention, respiratory tube 26 and positioning shield 22 are pre-curved along about the same arcuate curve such that minimal bending of respiratory  
20   tube 26 is required during positioning of laryngeal mask 10 around the laryngeal opening. Generally, and in one embodiment of the invention, respiratory tube 26 is composed of a material with a low coefficient of friction to facilitate the delivery of endotracheal tubes and related medical instruments through respiratory tube 26 outside of the patient's



laryngeal opening. Respiratory tube 26 generally comprises a material that allows it to deform radially to allow passage of endotracheal tubes and related medical instruments having large circular cross-sections, and return to its original cross-sectional shape upon the removal of the instruments. In specific embodiments, respiratory tube 26 returns to its original elliptical cross-sectional shape upon the removal of the instruments.

In one embodiment of the invention, at least one lumen 38 perforates distal end 24 to provide alternate airways in the event that that distal lumen 32 becomes obstructed during patient lung ventilation. Lumens 38 have diameters that are smaller than the diameter of distal lumen 32 and generally provide a ventilation alternative to distal lumen 32 and prevent the formation of a pressure differential between shield recess 36 and respiratory tube 26. Absent this differential, any object obstructing the distal lumen 32 will not become inextricably lodged within distal end 24. Lumens 38 may be any shape including, but not limited to circular, oval and slot-shaped.

Laryngeal masks 10 of the invention comprise an inflatable positioning shield 22 that includes recessed front portion 43. Recessed front portion 43 is generally made of the same material as the other portions of laryngeal mask 10. Generally, recessed front portion 43 comprises a material that makes it pliable. It is preferred that it comprises a material that makes it sufficiently pliable to cup the patient's trachea after inflation of positioning shield 22. This inhibits lateral movement of laryngeal mask 10 during use. Suitable materials that will impart pliability to recessed front portion 43 include polyvinylchloride ("PVC") and silicone. It should be noted, however, that other materials may be used that impart pliability that are within the scope of this invention including, but not limited to polyurethane, EVA, TPE, polyether block amide, or the like.

It should also be noted that recessed front portion 43 may not comprise a material that imparts pliability. Recessed front portion 43 may be rigid in accordance with the invention.

In one embodiment of the invention, and with reference to Fig. 9, recessed front  
5 43 portion of inflatable positioning shield 22 comprises at least one support member 51 that is adapted to stabilize posterior base 42 of inflatable positioning shield 22 or that is adapted to inhibit gastric aspirate, or other foreign matter, from entering the shield recess 36. Support member 51 may be any member that is adapted to impart stability or rigidity to posterior base 42. Support member 51 may also be any member that is adapted to  
10 inhibit foreign matter from entering the shield recess 36. In one embodiment of the invention, the support member is a raised horizontal runner that is a continuous extension of posterior base 42. In a more specific embodiment of the invention, recessed front 43 portion of inflatable positioning shield 22 includes a plurality of raised runners 51.

In a specific embodiment of the invention, laryngeal mask 10 does not comprise  
15 an inflatable positioning shield that includes a recessed front portion.

In accordance with the invention, distal end 24 terminates at an angle to its length, forming distal lumen 32 that is open to the interior of shield recess 36. In one embodiment, distal lumen 32 has about the same cross-sectional shape as the respiratory tube 26. Accordingly, and in one embodiment of the invention, distal lumen 32 has an  
20 elliptical cross-section. In another embodiment of the invention, distal lumen 32 has a diameter that is smaller than the diameter of proximal end lumen 30. It is believed that the shape of distal lumen 32 forces any endotracheal tubes or related medical instruments inserted toward the center of distal lumen 32 and in an upward direction, thereby leaving

space for the insertion and use of other medical instruments that have been inserted into the respiratory tube. It is also believed that the epiglottis is forced onto distal end 24 of respiratory tube 26, allowing any medical instruments inserted into respiratory tube 26 direct access to the oropharynx. Therefore, manual movement of the epiglottis is not  
5 required as with current laryngeal masks and methods of using such.

In one embodiment of the invention, and with reference to Figs. 1 and 3, distal lumen 32 comprises an upper portion and a lower portion, the upper portion having a larger diameter than the lower portion. This shape is generally referred to as a keyhole shape.

10 In another specific embodiment of the invention, distal lumen 32 comprises an upper and lower portion, which both have about the same diameter, which is smaller than the diameter of proximal end lumen 30 and distal lumen 32. In this embodiment, distal lumen 32 is slot-shaped. In a more specific embodiment of the invention, distal lumen 32 is also sufficiently pliable such that it opens upon assertion of pressure thereon and  
15 returns to its original shape when the pressure is released. Accordingly, endotracheal tubes and other related medical devices could be safely inserted into laryngeal opening by applying pressure onto distal lumen 32.

During use, laryngeal mask 10 is inserted through the oral cavity with peripheral portion 40 fully deflated. The smooth arcuate curve of laryngeal mask 10, including  
20 respiratory tube 26 and positioning shield 22, ensures proper positioning of laryngeal mask 10 within the anatomy surrounding the laryngeal opening. Upon proper positioning, as determined by resistance to further forward motion, peripheral portion 40 is inflated. When fully inflated, peripheral portion 40 exerts sufficient pressure against

the structures of the oropharynx, permitting positive lung ventilation to be performed, and allowing endotracheal tubes or related medical instruments to be inserted through respiratory tube 26 and into distal lumen 32. The inserted instruments are thereby directly aligned for passage into the laryngeal opening.

5           Removal of laryngeal mask 10 is normally the reverse of the insertion procedure described above. In some situations however, it is desired to remove laryngeal mask 10 without simultaneously removing or dislodging inserted endotracheal tubes or related medical instruments or devices passing through respiratory tube. You will find generally to Figs. 10 through 15, removal of laryngeal mask 10 under some circumstances is  
10   facilitated by means of a tube retainer, shown generally at 48.

          Tube retainer 48 comprises a connection adapter 50 and solid rod 52. In an alternate embodiment, tube retainer 48 additionally comprises end cap 68. Connection adapter 50 is composed of a soft semi-rigid material forming a truncated conical structure having at least one longitudinal ventilation groove 56. Ventilation groove 56 permits the  
15   passage of air around connection adapter 50 after insertion within an endotracheal tube, as shown in Figs. 13-15. The exterior surface of connection adapter 50 between each ventilation groove 56 is threaded or grooved with thread 60. Each thread 60 is angled and shaped so as to facilitate insertion of connection adapter 50 into an endotracheal tube by means of a longitudinally directed force applied to adapter 50. Alternatively, adapter  
20   50 may be screwed into place, and unscrewed, as desired. The conical nature of connection adapter 50 permits tube retainer 48 to fit securely within the opening of a variety of endotracheal tubes, generally ranging from standard size number 6 to standard size number 8 tubes. The present invention may be adapted as desired to accommodate

larger or smaller tubes, or both, without departing from the scope of the current invention. As tube retainer 48 is inserted within the opening of an endotracheal tube, the increasing exterior diameter of connection adapter 50 prevents insertion beyond a certain point, limited by the interior diameter of the endotracheal tube.

5           Solid rod 52 is a semi-rigid, circular, cross-section rod, where the cross-section is perpendicular to the longitudinal axis of the rod. Again, all cross-sectional references herein are perpendicular to the longitudinal axis. The length of solid rod 52 is sufficient to traverse the distance between a point external to a patient's oral cavity and the laryngeal opening. During the insertion of the tube retainer within an endotracheal tube  
10 or related medical instrument, the end of solid rod 52 that is external to the oral cavity may consist of a softer end cap 68. Of course, rod 52 may be used separately as an intubating stylet for direct visualization by unscrewing adapter 50 from rod 52 and placing cap 68 into the trachea directly. It should be noted, that rod 52 is a solid rod. Soft cap 68 is designed and configured to reduce potential tracheal trauma when used as  
15 an intubating stylet.

Figures 13-15 illustrate the use of tube retainer 48 during removal of laryngeal mask 10. As described above, the use of a tube retainer prevents the displacement of any inserted endotracheal tubes during removal of laryngeal mask 10. Connection adapter 50 of tube retainer 48 is secured to solid rod 52 and pass through respiratory tube 26.  
20 Connection adapter 50 partially enters the proximal opening of the inserted endotracheal tube 70 as shown in Fig. 13. The length of solid rod 52 is sufficient to extend beyond the oral cavity after insertion within endotracheal tube 70, allowing manipulation of the tube retainer as needed to insure secure insertion. As shown in Fig. 13, laryngeal mask 10

may then be removed from the oropharynx without dislodging endotracheal tube 70 by sliding laryngeal mask 10 along tube retainer 48. Tube retainer 48 allows force to be exerted through solid rod 52 and connection adapter 50 on endotracheal tube 70, resisting the tendency of endotracheal tube 70 to withdraw from the laryngeal opening as laryngeal mask 10 is removed. Once clear of the oral cavity, tube retainer 48 is then removed by unscrewing it from the endotracheal tube and allowing the endotracheal tube to remain in place within the patient's laryngeal opening. Laryngeal mask 10 is simply slid off retainer 48 either before or after tube retainer 48 is removed from the endotracheal tube.

Methods of manufacturing laryngeal masks are known in the art. Any known method, including injection molding, may be used to manufacture the laryngeal masks of the invention. Examples of suitable manufacturing methods are found in U.S. Pat. No. 6,261,401 to Pagan, U.S. Pat. No. 6,021,779 to Pagan and U.S. Pat. No. 5,391,248 to Brain.